INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

PHYTOSANITARY TREATMENTS FOR REGULATED PESTS

Secretariat of the International Plant Protection Convention
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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INTRODUCTION

SCOPE

This standard presents a list of treatments that are internationally recognized and intended for use by NPPOs to meet their phytosanitary requirements. The treatments provide the minimum requirements to achieve treatment of a regulated pest at a stated efficacy.

This standard also describes the requirements for submission and evaluation of a phytosanitary treatment for use as a phytosanitary measure.

This standard only applies to treatments for regulated pests and used on plants, plant products or other regulated articles in international trade, or for other phytosanitary purposes.

The scope of this standard does not include issues related to pesticide registration or other internal requirements for approval of treatment measures (e.g. irradiation). The inclusion of a phytosanitary treatment in the present ISPM does not create any obligation for a contracting party to approve the treatment, register it, or process it for use in its territory.

REFERENCES

*Glossary of phytosanitary term*s, 2005. ISPM No. 5, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

For the purpose of country consultation, this section also contains terms or definitions which are new or revised in the present draft standard. Once this standard has been adopted, the new and revised terms and definitions will be transferred into ISPM No. 5, and will not appear in the standard itself.

New term and definition:

treatment schedule	The elements of a treatment that are critical to achieving the stated efficacy.

OUTLINE OF REQUIREMENTS

Phytosanitary treatments may be required by contracting parties as phytosanitary measures to prevent the introduction and spread of pests of phytosanitary concern.

Treatments should fulfil certain requirements in relation to their efficacy, feasibility and applicability.

National Plant Protection Organizations (NPPOs) or Regional Plant Protection Organizations (RPPOs) submit a treatment for inclusion in the ISPM on phytosanitary treatments by providing information on the treatment, pest(s) and commodity(ies) or regulated articles concerned. The submission should include efficacy data on the treatment under laboratory or controlled experimental conditions, and also under operational conditions. The expected level of efficacy of the treatment should be stated in the submission and should be applicable to use of the treatment internationally. Information on the technical feasibility and commercial applicability of the treatment should be provided.

Submissions will be evaluated by the Technical Panel on Phytosanitary Treatments. After adoption by the Commission on Phytosanitary Measure (CPM), phytosanitary treatments will be incorporated into Annex 1 of this standard.

BACKGROUND

The purpose of the IPPC is "… *to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control* …" (Article I.1 of the IPPC, 1997). The requirement or application of phytosanitary treatments to commodities and regulated articles is a phytosanitary measure used by contracting parties to prevent the introduction and spread of regulated pests.

Article VII.1 of the IPPC 1997 states: "*... contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:*

a) *prescribe and adopt phytosanitary measures concerning the importation of plants, plant products and other regulated articles, including, for example, inspection, prohibition on importation, and treatment*."

Phytosanitary measures required by a contracting party should be technically justified (Article VII.2a of the IPPC, 1997).

For many years, National Plant Protection Organizations (NPPOs) have utilized phytosanitary treatments to prevent the introduction and spread of regulated pests. Many of these treatments are supported by extensive research data and others are used based on historical evidence which supports their efficacy. In practice, most countries use the same treatments or similar treatments for specified pests; however, there is currently no body to evaluate treatments for their efficacy and no central repository for listing such treatments. The Interim Commission on Phytosanitary Measures, at its sixth session in 2004, recognized the need for international recognition of phytosanitary treatments and approved the formation of a Technical Panel on Phytosanitary Treatments (TPPT) for that purpose.

REQUIREMENTS

1. Criteria for Treatments

Treatments for which a submission can be made include, but are not limited to: chemical, irradiation, heat, cold, controlled atmosphere. NPPOs and RPPOs should take into account other factors when considering phytosanitary treatments for approval, such as the effects on human health and safety, animal health and the environment (see the preamble and Article I.1 of the IPPC, 1997). Effects on the quality of the commodity should also be considered.

2. General Requirements for Phytosanitary Treatments

The NPPO or RPPO should ensure that phytosanitary treatments are:

- effective in killing, inactivating, or removing target pests, rendering pests infertile/incapable of further development or devitalizing pests associated with the target commodity(ies) or regulated article(s). The level of efficacy of the treatment should be stated (quantified or expressed statistically). Where statistical data is unavailable, other evidence that supports the efficacy (i.e. historical and/or practical information/experience) should be provided.
- well documented and show that the efficacy data has been generated using appropriate experimentation procedures, including an appropriate experimental design. The data supporting the treatment should be verifiable, reproducible and based on statistically sound methods or on established and accepted international practice and, where possible, it should have been published in a peer-reviewed journal.
- feasible and applicable for use in international trade or other movement, e.g. for research purposes.

3. Specific Requirements for Phytosanitary Treatments

Information on phytosanitary treatments should include the following elements:

- summary information
- efficacy data in support of the submission of a phytosanitary treatment
- information on commercial feasibility and applicability.

3.1 Summary information

The summary information should be submitted by NPPOs or RPPOs utilizing the form provided in Annex 2 and should include:

- name of the treatment
- name of the NPPO or RPPO
- contact details of a person responsible for submission of the treatment
- description of the treatment (treatment type, target pest, treatment schedule, other information)
- reason for submission, including its relevance to existing ISPMs.

3.2 Efficacy data in support of the submission of a phytosanitary treatment

The source of all efficacy data provided in the submission (published or unpublished) should be provided. Supporting data should be presented clearly and systematically.

3.2.1 Efficacy data under laboratory/controlled conditions

The pest life-cycle stage for the treatment should be specified. Usually, the most resistant stage of the pest(s) is the stage for which a treatment is proposed and established. However, practical considerations should be taken into account, as well as pest control strategies aimed at exploiting vulnerable or specific stages of a pest.

If efficacy data is submitted for a life-cycle stage that is not considered to be the most resistant, rationale for this (e.g. a summary of the appropriate pest control strategy) should be provided. The efficacy data provided should specify the statistical level of confidence supporting efficacy claims made for treatment of the specified life-cycle stage.

Where possible, data should be presented on methods used to determine the effective dose/treatment to demonstrate the range of efficacy of the treatment (e.g. dose/efficacy curves). Treatments can only be adopted for the conditions under which they were tested. Additional information should be provided to support any extrapolation if the scope of a treatment is to be extended (e.g. extending the range of temperatures or the inclusion of other varieties). The materials and methods utilized in the experiments should be suitable for the use of the treatment at the stated efficacy.

The data provided should include detailed information, but is not limited to, the following elements:

Pest information

- identity of the pest to the appropriate level (e.g. strain, biotype, physiological race and life stage, laboratory or field strain)
- conditions under which the pests are cultured/reared or grown
- biological traits of the pest relevant to the treatment (e.g. viability, genetic variability, weight, developmental time, fecundity, freedom from disease or parasites)
- method of natural/artificial infestation
- determination of most resistant species/life stage (in the commodity where appropriate).

Commodity/regulated article information

- commodity type/cultivar (where varietal differences impact on treatment efficacy, data should be provided for all varieties under consideration)
- conditions of the commodity, for example:
  - whether it was free from disease/non-target pest infestation or pesticide residue
  - size, shape, weight, stage of maturity, quality, variety, etc.
  - infested at a susceptible growth stage
- type of regulated article.

Experimental parameters

- level of confidence provided by the laboratory testing, method of statistical analysis, and the data supporting that calculation (e.g. number of subjects treated, number of replicate tests, controls)
- experimental facilities and equipment
- experimental design (e.g. randomized complete block design)
- experimental conditions (e.g. temperature, relative humidity, diurnal cycle)

- monitoring of critical parameters (e.g. exposure time, dose, temperature (target commodity and air), relative humidity)
- methodology to measure the effectiveness of the treatment (e.g. whether mortality is the proper parameter, whether the end-point mortality was assessed at the correct time, mortality or sterility of treated and control group)
- determination of efficacy over a range of critical parameters, where appropriate, such as exposure time, dose, temperature, relative humidity and water content.

3.2.2 Efficacy data using operational conditions

The treatment developed under laboratory conditions should also be validated by testing under operational or simulated operational conditions. Results of these tests should confirm that the application of the treatment schedule achieves the stated efficacy under conditions in which the treatment will be used. Where treatment specifications differ in operational trials, the test protocol modifications should be indicated.

Data may be presented from preliminary tests to refine the treatment schedule to establish the effective dose (e.g. temperature, chemical, irradiation) under operational conditions.

In some cases the method of achieving the effective dose will be different from the method established under laboratory conditions. Data should be provided that supports any extrapolation of laboratory results.

The same data requirements as listed in section 3.2.1 should also be provided for these tests. Other data required are listed below:

- factors that affect the efficacy of the treatment (packaging, packing method, stacking, timing of treatments, pre/post packaging or processing, in transit, on arrival). The circumstances of the treatment should be stated, for example the efficacy of a treatment may be affected by packaging, and data should be provided to support all the circumstances that are applicable.
- monitoring of critical parameters (dose, temperature (commodity and air), relative humidity). For example:
  - the number and placement of gas sampling lines (fumigation)
  - the number and placement of temperature/humidity sensors.

In addition, any special procedures that affect the success of the treatment (e.g. to maintain the quality of the commodity) should also be included.

3.3 Information on commercial feasibility and applicability

The phytosanitary treatment should be feasible and applicable internationally.

Information should be provided to support the phytosanitary treatment including such items as:

- feasibility of carrying out the phytosanitary treatment (includes ease of use, risks to operators, technical complexity, training required, equipment required, cost)
- extent to which other NPPOs have approved the treatment as a phytosanitary measure, if known
- availability of expertise needed to apply the phytosanitary treatment internationally
- versatility of the phytosanitary treatment (e.g. application to a wide range of countries/pests/commodities)
- the degree to which the phytosanitary treatment complements other treatments or procedures (e.g. potential for the treatment to be used as part of a systems approach for one pest or to complement treatments for other pests)
- feasibility of having the phytosanitary treatment accepted at the international level
- consideration of potential non-target effects (e.g. impacts to environment, to non-target organisms)
- applicability of treatment with respect to specific commodity/pest combinations
- commercial relevance
- technical viability
- human and animal health and safety

- commodity quality.

Treatment schedules should adequately describe the method for applying the treatment in a commercial environment.

4. Evaluation and Publication of Phytosanitary Treatments

The Technical Panel on Phytosanitary Treatments will prioritize and evaluate the submissions for their suitability (see Appendix 1). After adoption by the CPM, phytosanitary treatments will be incorporated into Annex 1 of this standard.

ANNEX 1

APPROVED PHYTOSANITARY TREATMENTS[1]

Phytosanitary treatments will be incorporated into this Annex after adoption by the CPM.

[1] This annex is an official part of the standard.

ANNEX 2

INFORMATION REQUIRED FOR SUBMISSION OF A PHYTOSANITARY TREATMENT[2]

The following summary information should be provided (see section 3.1). This cover page is designed to assist the evaluation process. The information required in sections 3.2 and 3.3 should be appended to this cover page. Text in brackets is given for explanatory purposes.

Name of treatment (Provide enough detail to identify the treatment. For example, cold treatment of navel oranges for Mediterranean fruit fly): Indicate ISPM number in the box if submission is applicable to an ISPM ☐	
Name of NPPO or RPPO:	
Name of person responsible for the submission of the treatment (contact person:	
Position and/or title:	
Affiliation:	
Complete mailing address:	
Phone:	
Fax:	
Email:	

[2] This annex is an official part of the standard.

Treatment description

Treatment type (e.g. chemical, irradiation, heat, cold):

Target commodity(ies)/regulated article(s) (include taxonomic classification, description of commodity, state of preservation/processing or maturity (e.g. fruit, plants for planting, part of plant, wood), cultivar or variety, intended use, description of regulated article (e.g. ship, container, soil, machinery, wood, silo) as appropriate):

Target pest(s): the identity of the target pest(s) (taxonomic information including strains, biotypes and, where appropriate, life stage(s))

Schedule (include description such as active ingredient, dose, duration and temperature):

Other information (delivery method, pre/post handling conditions, etc.):

Reason for submission: (describe why the treatment is needed; where a treatment is widely used, include the countries where approved. Also, is it relevant to any existing ISPMs?)

Signature: _____
Date submitted: _____

Send submissions to:
E-mail: ippc@fao.org **Fax:** (+39) 06 5705 4819
Mail: IPPC Secretariat (AGPP), Food and Agriculture Organization of the UN, Viale delle Terme di Caracalla, 00100 Rome, Italy

APPENDIX 1

CRITERIA FOR PRIORITIZING AND EVALUATING SUBMITTED INFORMATION ON PHYTOSANITARY TREATMENTS[3]

1. Priorities

Factors for determining priorities include:

- use of the phytosanitary treatment as an alternative treatment to methyl bromide
- value/volume of trade affected by phytosanitary treatment
- relevance and value to a standard under development requiring phytosanitary treatment(s)
- frequency with which a phytosanitary treatment is linked to a trade issue (e.g. disputes or need for repeated bilateral discussions)
- relevance and utility to developing countries
- emergency need for the phytosanitary treatment
- long term benefits of the phytosanitary treatment (e.g. chemicals likely to be banned or withdrawn would be low priority)
- issues associated with deferring or rejecting the phytosanitary treatment
- applicability to a wide range of commodities and pests.

2. Evaluations of Submissions

Submissions will be considered by the Technical Panel on Phytosanitary Treatments only when the information outlined in section 3 of ISPM No. -- (*Phytosanitary treatments for regulated pests*) is complete.

The Technical Panel on Phytosanitary Treatments will exercise due respect for confidentiality where sensitive information is provided by the applicant.

In evaluating submissions, the Technical Panel on Phytosanitary Treatments will consider the following criteria:

- the experience or expertise in the subject area of the laboratory, organization and/or scientist(s) involved in producing the data
- whether the data was published. More weight may be given to data that was published in international peer-reviewed journals
- the availability of experts to evaluate the phytosanitary treatment
- whether researchers utilized a quality assurance or accreditation program in the development and/or testing of the phytosanitary treatment.

Treatments will only be approved for the conditions under which they were tested, unless data is presented to support extrapolation (e.g. to apply the treatment to a range of pest species or commodities).

3. Outcome of Evaluation

Once a submission has been evaluated and the treatment has been found to meet the criteria for adoption internationally, it will be recommended as an international treatment. After adoption by the CPM, the phytosanitary treatment will be incorporated into Annex 1 of ISPM No. --: *Phytosanitary treatments for regulated pests*.

If the submission fails to meet the criteria for adoption internationally, the reason(s) will be communicated to the contact identified on the submission. There may be a recommendation to provide additional information or to initiate further work (e.g. research, field testing, analysis).

[3] This appendix is not an official part of the standard. It is provided for information only.